

## **REMARKS**

Claims 1-25, 27-52, and 54-93 constitute the pending claims in the present application. Claims 26 and 53 have been canceled by Applicants. Claims 1-16 (incorrectly identified as claims 1-30 in the Office Action mailed May 14, 2003), 32-46, and 59-93 have been withdrawn by the Examiner. Amendments presented in this response are made solely to expedite prosecution of the claims in the present application. Applicants reserve the right to prosecute claims of similar or differing scope in subsequent applications. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

### ***Claim Rejection – 35 U.S.C. § 112***

Claims 17-31 and 47-58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has objected to the term “lower alkyl” in claims 17 and 47 as a relative term rendering the claims indefinite.

Applicants respectfully direct the Examiner to the specification, page 22, last paragraph through page 23, first full paragraph. On page 23, the specification defines a lower alkyl as “having from one to ten carbons, more preferably from one to six carbon atoms in its backbone structure.” Further, on page 22, the specification discloses that lower alkyl “is intended to include both ‘unsubstituted alkyls’ and ‘substituted alkyls,’” and gives specific examples of suitable substituents.

Applicants submit the term “lower alkyl” is not indefinite and is clearly defined in the specification. In light of this definition, one of skill in the art would understand what is meant by lower alkyl and would be apprised of the scope of the claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

### ***Double Patenting Rejections***

1. Claims 17-24 and 47-51 are rejected under the judicially created doctrine of double patenting over claims 1-35 of U.S. Patent No. 6552016 (“the ‘016 patent”), allegedly to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent.

Applicants have amended independent claims 17 and 47 to include the limitations of dependent claims 26 and 54, respectively, which were not rejected on this basis. Applicants submit these amendments render this double patenting objection moot. Accordingly, Applicants request reconsideration and withdrawal of the rejection in light of the claims as amended.

2. Claims 25-31 and 52-58 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-35 of the '016 patent. Applicants respectfully traverse.

According to MPEP § 804.II.B.1, a one-way determination of obviousness is needed if the application at issue is the later filed application. An obviousness-type rejection should make clear “(A) the differences between the inventions defined by the conflicting claims . . . and (B) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent.” MPEP § 804.II.B.1 This analysis parallels the determination of obviousness under 35 U.S.C. § 103(a) and the same factual inquiries must be employed. MPEP § 804.I. However, unlike in a § 103(a) analysis, “[w]hen considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claims of a patent, the **disclosure of the patent may not be used as prior art.**” MPEP § 804.II.B.1 (emphasis added).

To establish a prima facie case of obviousness of the claims of the present application, the Examiner must establish that (1) the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combine references to make the claimed invention, (2) the proposed modification of the prior art must have had a reasonable expectation of success, and (3) the prior art reference must teach or suggest all the limitations of the claims. *See Karsten Mfg. Corp. v. Cleveland Gulf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991); *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970).

Applicants submit that the Examiner has failed to establish all three factors required to show the obviousness of the claims at issue. First of all, the claims of the '016 patent do not suggest that the claimed preparation “comprising a sterile excipient and a compound” may be

included in “*an aqueous solution of a dissolved physiologically acceptable salt and a pharmaceutically acceptable salt of a compound*,” explicit limitations of independent claims 17 and 47 of the present application as amended. The claims of the ‘016 patent do not suggest claims directed to aqueous solutions comprising a compound further including (1) a solute, (2) ranges in osmolarity and pH, or (3) suitability for topical administration. There is no language directed to any of these variables in the claims of the ‘016 patent.

Secondly, the ‘016 patent fails to teach or suggest all the limitations of the claims of the present application. The independent claims of the ‘016 patent are directed to a “sterile pharmaceutical excipient and a compound” represented by a general formula having a variety of defined substituents. Every dependent claim limits the general formula to a narrower set of substituents. None of the claims teaches or suggests the limitations in the claims at issue, specifically, aqueous solutions comprising a compound further including (1) a solute, (2) ranges in osmolarity and pH, or (3) suitability for topical administration. As mentioned above, there is no recitation of any of these features in the claims of the ‘016 patent. Thus, a *prima facie* case of obviousness-type double patenting has not been established.

Assuming, arguendo, that one skilled in the art could reasonably prepare an aqueous solution of a salt form of a compound disclosed in the ‘016 patent, the mere fact that the teachings of the ‘016 patent claims could be so modified does not make the modifications obvious unless the ‘016 patent claims suggested the desirability of the modification. *See In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Applicants submit that the ‘016 patent claims failed to suggest the desirability of any of the modifications claimed in the present application

Furthermore, the Examiner improperly relied on the teachings of the ‘016 patent as prior art in concluding the present invention is obvious over the ‘016 patent. The Examiner states explicitly that the so-called “minor variations and modifications . . . [are] well within the skilled level of artisan having ordinary skill in the art, and commonly practiced in the art as evidenced by the specification of the patented disclosure(US’016) [sic], and thus, obvious.” (emphasis added). The Examiner failed to provide any other evidence than the proscribed specification of the ‘016 patent for concluding the subject matter of the present application is obvious. No full and reasoned explanation supports a finding of obviousness. However, the legal test for

obviousness does not rest solely on a question of enablement; the rejection fails to demonstrate that the limitations were taught by the claims of the '016 patent, or that there was motivation to arrive at the particular combination of elements now claimed.

Accordingly, Applicants request reconsideration and withdrawal of this rejection.

***Rejoinder of Dependent Claims***

Applicants respectfully request rejoinder and examination of the claims of Groups IV, VI, X, and XII. The claims of Groups IV and VI, respectively claims 33 and 35 (incorrectly identified in Paper No. 7 as claims 32 and 34), and Groups X and XII, respectively claims 60 and 62, depend upon the claims of Group II or VIII and contain all the limitations thereof.

Applicants respectfully direct the Examiner's attention to MPEP 809, which states that "[a]ny claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability." Accordingly, claims 33, 35, 60, and 62 must be rejoined.

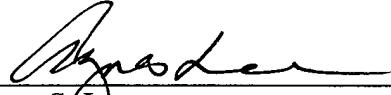
## **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,

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